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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,826	02/22/2002	Frank Himmelsbach	5/1315US	7064

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EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/04/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,826

Applicant(s)

HIMMELSBACH ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,7 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,14 and 20 is/are rejected.
- 7) ☒ Claim(s) 2,3,7,13 and 15-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority Papers

The priority papers received are three: 10117803 and 10203486 and 10109021.

The fourth is not in the file. A replacement copy will be needed.

The translations have now been received for all seven priority papers.

The rejections over Kanstrup and Chackalamannil were overcome by amendments to the claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 37-4895.

In JP 37-4895, see the attached index sheet which shows the relevant species. This corresponds to the R4 = NR15R16 choice, where R16 is diethylamino propyl. The sole difference is that the claim requires R15 as methyl, while the reference has H. Such a variation is considered obvious because of the close structural similarity. See *In re Hoeksema*, 154 USPQ 169; *Ex parte Weston*, 121 USPQ 428; *Ex parte Bluestone*, 135 USPQ 199; *In re Doebel*, 174 USPQ 158. Note also *In re Jones*, 21 USPQ2d 1942, which states at 1943 "Particular types or categories of structural similarity without more, have, in past cases, given rise to *prima facie* obviousness"; one of those listed is "adjacent homologues and structural isomers".

The traverse is unpersuasive. The declaration is unpersuasive for two reasons:

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1. The declaration presents conclusions without supporting facts, and as such it is entitled to little or no weight, cf. *In re Etter*, 225 USPQ 1, 6; *In re Grunwell*, 203 USPQ 1055, 1059; *In re Buchner*, USPQ2d 1331; *In re Chilowski*, 134 USPQ 515,521; *In re Brandstadter*, 179 USPQ 286, 293-294, *In re Thompson*, 192 USPQ 275; *Ex parte George* 21 USPQ2nd 1058, 1062. No evidence was presented that the desired compound was not present along with the tricyclic compound, nor was evidence presented that the prior art procedure was followed.

2. The fact that declarant failed to make the prior art compound is not necessarily dispositive of the issue; it does not necessarily render the reference non-enabled. As was stated in *In re Lamberti*, 192 USPQ 278 (CCPA 1976), "At best, appellants have merely shown that it is possible to follow the process in one example each of MacGregor and Cisney without success. And even then, there is no showing that one of ordinary skill in the art, making adaptations within the skill of the art, could not have successfully carried out each process." Applicants have not tried any such adaptations. The same thought appears in *In re Michalek*, 74 USPQ 107, which states, "With respect to the experiments described in the affidavits it must be said that in a patent it is to be presumed that a process, if used by one skilled in the art, will produce the product alleged by the patentee and such presumption is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product. Skilled workers would as a matter of course, in our opinion, if they do not immediately obtain desired results, make certain experiments and adaptations and we agree with the argument of the solicitor that it is not a difficult matter to carry out a process in such fashion that it will not be successful and, therefore, the failures of experimenters who

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have no interest in succeeding should not be accorded great weight, citing *Bullard Company et al. v. Coe*, 147 F.2d 568, 64 USPQ 359 . Possibly more extensive experiments than were made by the affiants herein might have produced a different result.” Likewise is *Freeman v. Minnesota Mining and Manufacturing Co.* 9 USPQ2d 1111, “Freeman has the burden of proving that there was no operable technique for making polyethylene supports or that polyethylene itself was an inoperable material. ...Freeman did not offer any proof that one of ordinary skill in the art could not injection-mold the structure of Figure 15 in 1975.” A single failure or two cannot meet such a burden of “there was no operable technique”. See also *Ex parte Gray* 10 USPQ2d 1922, 1928 which states, “we are of the opinion that, to raise the question of nonenablement, appellants must, at the very least, provide a declaration by a person having ordinary skill in the subject art that no method was known to him prior to the claimed invention whereby the claimed material might have been synthesized.” See also *In re Sasse*, 207 USPQ 107, and also *In re Collins* 174 USPQ 333, which states, “we do agree with the solicitor that Sweedyk's affidavit fails to establish that there was no known or obvious way to make heat exchangers falling within the scope of appellant's claims.”

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is nothing in the specification which says that these compounds can treat the underlying diseases or conditions which require allograft transplantation. The term "allograft transplantation" simply means the transplantation of an organ from one human (dead or alive) to another. Thus, this claim covers treatment of any disease or condition that results in the need of transplantation of skin, heart, lung, liver, meniscal cartilage, bone marrow, kidney, cornea, limbal stem cell, islet, larynx, hand, trachea, many different types of bone, etc. There is a colossal range of degenerative conditions, cancers, viral, bacterial and parasitic infections, immunological disorders, burns or other conditions which could result in the need for such transplantation, and the specification does not state that these compounds could treat them generally.

Claims 2,3,7,13,15-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.



Mark L. Berch
Primary Examiner
Art Unit 1624

August 1, 2003